DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. 7,497,997 (hereinafter "Glezer").

Glezer teaches an assay cartridge which may comprise reagents for carrying out an assay such as binding reagents, detectable labels, etc. The reagents may be present in liquid form, solid form and/or immobilized on the surface of solid phase supports present in the cartridge. Column 37, lines 31-51. (See related provisional application on page 14-17 disclosing an assay cartridge and its components; page 9 and 29 disclosing reagents such as labeled binding partner of the analyte of interest or a labeled competitor that competes with the analyte of interest for a binding partner of the analyte of interest; page 62 disclosing that these reagents may be stored in dry or wet form in the assay chamber.)

The sample chamber may contain dry reagents used in carrying out the assay that reconstitute on addition of a liquid sample. Column 39, lines 9-36; and column 43,

lines 56-65. (See page 62 of the provisional application disclosing that the reagents may be in dry form implies that the dried reagents are reconstituted on addition of a liquid sample.)

The zone in which dried reagents are deposited may be prescribed by a boundary which confines the volume to a specific region of a substrate. The boundary surface may be raised or lowered (preferably, raised). Column 46, line 66 to column 47, line 18. The zone may for example be defined by a depression cut or molded into the substrate. The reagent can then be dispensed onto the substrate within the zone boundary. Column 47, lines 19-35. Detection chambers comprise immobilized binding reagents. Column 55, lines 34-48. (See pages 21-22 of the provisional application disclosing that the electrode surface is bounded by a dielectric surface that is raised or lowered; and see page 49 disclosing immobilization of reagents on a surface such as an electrode surface, and defined by a depression.)

Assay reagents may be immobilized. One may attach antibodies, proteins, enzymes, cells, cell receptors, etc.

Glezer also discloses forming a plurality of assay domains on a surface. Column 5, lines 9-26. The assay reagent in each domain may be the same or may be different. Assay reagents that may be used include, but are not limited to, antibodies, fragments of antibodies, proteins, enzymes, enzyme substrates, inhibitors, cofactors, antigens, haptens, lipoproteins, liposaccharides, cells, sub-cellular components, cell receptors, membrane fragments, viruses, nucleic acids, antigens, lipids, glycoproteins, carbohydrates, peptides, amino acids, hormones, protein-binding ligands,

pharmacological agents, membrane vesicles, lipsomes, organelles, bacteria or combinations thereof. Column 5, lines 27-36. (See provisional application on page 8.)

(It is also noted that the disclosure of the Glezer patent relied upon in the rejection above is also disclosed in the related provisional application, 60436569, as noted above, and is thus given the priority date of December 26, 2002 of the provisional application.)

As to Applicant's claim 3, the substrate (i.e., component of the cartridge or entire cartridge) is equivalent to a cell culture substrate having an area for culturing a cell. The portion of the cartridge which includes the dried reagent is equivalent to an area for culturing a cell containing a biologically active substance having a biological activity to the cell. It is noted that the area holding dried reagent is capable of functioning as a "culturing area". Moreover, such area holding the dried reagent is exposed on the surface of the substrate (column 46, line 66 to column 47, line 18.) Also, Glezer discloses a plurality of assay domains and reagents (which may be the same or different (column 5, lines 9-36) and thus discloses that the substrate (culturing area) contains at least two biologically active substances. It is also disclosed that the assay reagents that may be used include, but are not limited to, antibodies, cell receptors, glycoproteins, etc. Column 5, lines 27-36. (See provisional application on page 8.) Thus Glezer discloses examples of assay reagents that have biological activity to a cell.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 7,497,997 (hereinafter "Glezer").

Glezer has been discussed above. However Glezer is silent as to the substrate (or assay domains) containing different amounts of at least two biologically active substances as a function of position. However determining an amount of an assay reagent that is necessary for a particular assay requires only routine skill in the art, and it is predictable that the Glezer invention may be used for assays in which the necessary amounts of assay reagents include differing amounts. Moreover, it is noted that the plurality of assay domains in Glezer are in different positions on a substrate (column 5, lines 9-26), and thus such differing amounts of biologically active substances are provided as a function of position.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 7,497,997 (hereinafter "Glezer") in view of US 7,410,798 (hereinafter "Mandalam").

Glezer has been discussed above. However Glezer is silent as to at least two biologically active substances being IGF-1 and bFGF.

However Mandalam discloses pPS cells cultured to make differentiated cells of various commercially and therapeutically important tissue types. Disclosed for example are methods for obtaining highly enriched populations of cells of the neural lineage. Cells are changed to a culture medium containing one or more neurotrophins and one or more mitogens (such as epidermal growth factor, basic fibroblast growth factor [bFGF], platelet-derived growth factor, insulin-like growth factor 1 [IGF-1], and erythropoietin). Column 15, lines 14-33.

Thus Mandalam shows that use of IGF-1 and bFGF are known in the art for culturing cells for differentiation. Glezer teaches that assay reagents include cells, and thus it is predictable by the skilled artisan that such reagents disclosed by Mandalam may be used in the Glezer device as may be desirable as part of cell based assays.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 7,497,997 (hereinafter "Glezer") in view of US 5,723,331 (hereinafter "Tubo") and further in view of US 7,410,798 (hereinafter "Mandalam").

Glezer has been discussed above. However Glezer is silent as to at least two biologically active substances being IGF-1 and bFGF and BMP-2.

However Tubo discloses polypeptide growth factors that may be added to the chondrogenic cells in the pre-shaped well to enhance or stimulate the production of

cartilage specific proteoglycans and/or collagen. Preferred growth factors include, but are not limited to, insulin-like growth factor (IGF), basic fibroblast growth factor (bFBF), the bone morphogenic factors (BMPs) including BMP-2. However, these particular compounds are not limiting. Any compound or composition capable of stimulating or inducing the production of cartilage specific proteoglycans and collagen may be useful in the practice of the instant invention. Column 7, lines 24-43.

Thus Tubo shows that use of IGF and bFGF and BMP-2 are known in the art for adding to chondrogenic cells to enhance or stimulate the production of cartilage. Glezer teaches that assay reagents include cells, and thus it is predictable by the skilled artisan that such reagents disclosed by Tubo may be used in the Glezer device as may be desirable as part of cell based assays.

However Tubo lists insulin-like growth factor (IGF) but does not specifically mention IGF-1. However, IGF-1 is a known growth factor as shown by Mandalam (column 15, lines 14-33), and thus use of IGF-1 as the specific IGF disclosed by Tubo would have been obvious to the skilled artisan.

Response to Arguments

Applicants have amended the claims and assert that Glezer and the prior art do not disclose such combination of limitations as claimed. This is not persuasive for the reasons set forth above.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Malmqvist 6,200,814, discloses a gradient of amount of ligands may be provided (col. 14, lines 26-37.)

Ivarrson, 6,493,097, discloses simultaneous monitoring (column 7, line 60 – column 18, line 7) and presenting surface concentration changes (column 23, lines 53-64.)

Tashiro, 7,541,195, discloses a substrate for a microarray, the substrate having protruding spots for immobilizing biomolecules on the top surface of the protruding spots.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN Y. LAM whose telephone number is (571)272-0822. The examiner can normally be reached on Mon.-Thurs. 9-7:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ann Y. Lam/
Primary Examiner, Art Unit 1641